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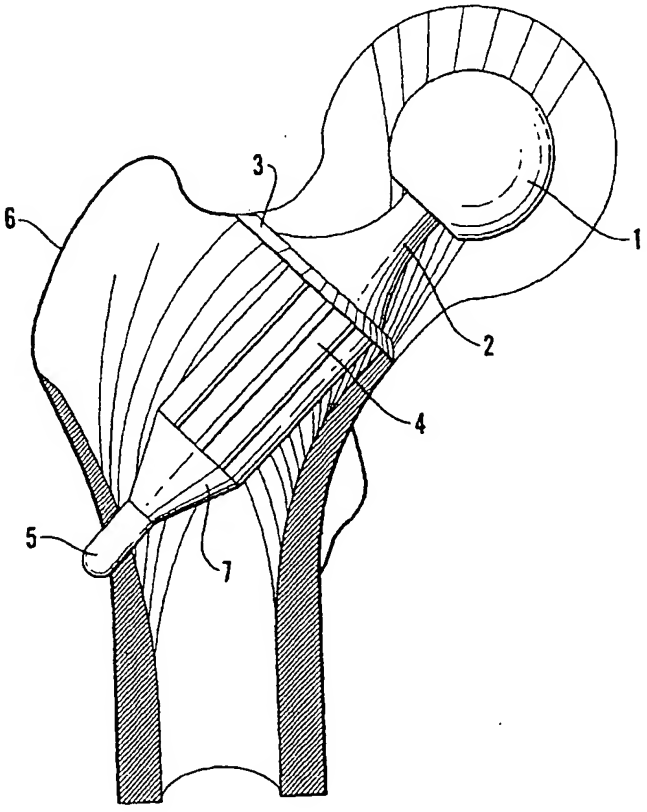
(54) Title: CONSERVATIVE HIP



(57) Abstract: A conservative hip prosthesis is provided which can be introduced entirely from the resected femoral head. The prosthesis includes a femoral head (1), a collar (3) for abutment onto a resected surface of the femoral head and a neck portion (2) for carrying the stem. The stem comprises a barrel (4) which is generally circular or elliptical in section having a distal projection (5) for engagement in the lateral cortex, wherein the portion between the distal projection and the barrel is tapered.

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CONSERVATIVE HIP

The most commonly used method for the treatment of the arthritic hip is total hip replacement. For the femur, the femoral head and neck are resected and a metallic stem about 150 mm in length is cemented into the femoral canal using acrylic cement. The upper part of the stem has a metallic femoral head attached. This head articulates into a hemispherical plastic socket, which is cemented into the acetabulum. Another scheme is where the components are press-fit into the bones without the use of cement. In this case specially adapted surfaces are usually used for bone attachment. The present invention concerns primarily an alternative scheme for the femoral component.

Total hip replacement as described above was developed in the 1960's and has been used to treat millions of patients with a remarkably high success rate. In elderly patient groups, a survivorship of over 90% at ten years follow-up is not uncommon. However, in younger and more active patients, the survivorship is much lower. Many variations in total hip design have been introduced in an effort to increase the durability of the components. For example, the cementing techniques have been improved. Stronger materials have been introduced. Porous or bioactive coatings have been applied to the stems in uncemented versions. The wear resistance of the bearing surfaces has been increased.

Notwithstanding a gradual improvement in results over the years, the results are still not sufficiently durable that the younger active patient groups can be treated with the confidence that the device will last their lifetime. The failure processes are inherent in the design of the total hip, with aseptic loosening being the most common. This is a

multi-factorial process involving micromotion at the cement-bone interface, the formation of fibrous tissue, the ingress of wear particles, and stress protection of strategic regions of bone which weakens the support of the implant, making it more susceptible to increased micromotion. With time, weight and activity level being the influencing factors, it can be appreciated that there is strong likelihood that a revision procedure will be necessary at least once in patients with a life expectancy of say 20 years or more.

The main problem with a revision procedure as far as the patient is concerned is that a considerable amount of bone of the upper femur is destroyed in the loosening process, and during the removal procedure at revision surgery. The subsequent revision implant is necessarily larger and longer in order to gain sufficient fixation. The survivorship of such devices is usually less than that of the primary procedure. Moreover, should that device fail, the prognosis is very poor indeed. Hence, there is a strong rationale for the use of a conservative device at the primary stage which involves interfacing with far less of the femur than does a conventional total hip. The goals of such a conservative device are that it will be easy to insert and will have a survivorship similar to that of a conventional total hip. Even if the survivorship was slightly less, there is still a justification for its use. If the conservative hip is suitably designed and if it were to fail by loosening or other reason, then its removal would involve little destruction of the femoral bone. The revision procedure would then be equivalent to the use of a primary total hip. Thereby, the patient would have gained a substantial time period, say 10 years or more.

Conservative approaches are not new. From the 1970's to the present, various 'surface replacements' have been attempted using combinations of metal, ceramic and polyethylene for the components; and press-fit, cement, porous or HA for fixation. There have been several problems with surface replacement to date:

- the femoral head has remodelled inside the femoral component, primarily by resorption over a substantial part of the interface;
- this has led to subsequent degradation of the implant-bone interface and overall loosening;
- fracture of the femoral neck level with the rim of the head component, although the risk can be minimized by avoiding excess reaming and by details of component design;
- excessive reaming of the socket;
- in cases of avascular necrosis of the femoral head, or severe osteoarthritis, the femoral head has been misshapen and unable to support the femoral component at the required offset.

Some attempts to provide satisfactory conservative hip designs are shown in Figure 1. Townley's TARA design (Figure 1B) is a modification of a standard surface replacement. Most of the head is removed using a transverse cut, producing compressive forces on the bone surface, greatly reducing the trabecular remodelling problem. The short stem further improves the stability. Thrust-plate designs (e.g. Hugger-Jacob) (Figure 1C) have met with some success in clinical follow-up, and further improvements are possible to this type using surface textures and coatings for

osseointegration. Advantages of this configuration are that good initial stability can be obtained to allow for osseointegration, and a normal modular head can be used. A key characteristic of this design is that a proportion of the varus bending is transmitted by the neck-collar. A disadvantage of the thrust plate system is that access is required to the lateral side below the greater trochanter.

Concerning standard stemmed hips, but with reduced stem length, finite element analysis of stems with a lateral flare indicates that, for high neck cut, the stem carries only a small bending movement, allowing its length to be shortened considerably. This provides the possibility of a 'proximal plug' type of conservative hip. In this type, osseointegration can occur over a large surface area. Preserving part of the femoral neck for bone support is used in the Mayo Conservative design (Figure 1F). Other conservative hip schemes include metal shrouds which cover regions of the outer proximal femur. Such designs could have application for abnormal femoral geometries, and even for some revisions. From the acetabular perspective, those conservative designs which incorporate a femoral trunnion to use a standard modular head, have an advantage for restoring the required head offset.

This invention uses some of the design features of previous designs, such as described above, but adds certain refinements. The original concept is that the design is based on the principle of transmitting the forces through the trabeculae between the femoral head and different endosteal regions of the upper femur in as physiological a way as possible.

According to one aspect of the present invention there is provided a conservative hip prosthesis which comprises a stem for introduction into the femur, a collar for abutment on a resected surface of the femoral neck and a neck portion for carrying a head, the stem being in the form of a generally cylindrical barrel portion having a distal projection for engagement in the lateral cortex, wherein an intermediate portion between the distal projection and the barrel portion is tapered towards the distal end.

Preferably, the intermediate portion is shaped as a generally right circular or elliptical cone.

The intermediate portion may have rounded sides when viewed in cross-section.

The generally cylindrical portion of the stem is preferably tapered towards the distal projection but to a lesser degree than the intermediate portion.

In order to stimulate integration of the prosthesis into the femur, the stem (and particularly all or part of the barrel) are provided with surface irregularities such as depressions, slots, grooves, projections or holes, typically in the range of 0.5 to 2 mm in diameter or width. Such irregularities can be made e.g. by grit blasting. Alternatively or additionally, the surfaces may be provided with an hydroxyapatite coating.

In another aspect of the invention there is provided a conservative hip prosthesis comprising a stem portion, a collar portion and a neck portion, wherein the stem portion is formed with longitudinal cutting means so that on introduction into the femur, the cutting means cut into the bone thus improving stability of the prosthesis in the femur.

The invention also includes a conservative hip which comprises a modular head on a neck, attached to a collar which is adapted to locate on the surface of the lower femoral neck which has been resected at 35-55 degrees to the horizontal, the head being attached to a barrel which projects towards the lateral cortex, the barrel being distally tapered, and having a distal spigot for projection into a hole in the lateral cortex; the surfaces of the barrel and collar being adapted to transmit force in a similar manner to that of the trabecular bone within the upper femur.

The invention will be illustrated by the following description and specific embodiments as shown in the accompanying drawings, in which:-

Figure 1A to 1F are longitudinal sections through prior art conservative hip designs;

Figures 2A to 2D are photographs of the resected head of a human femur which have been resected for conservative hip installation, showing the small amount of bone which is cut away;

Figure 3 is a longitudinal section through a first embodiment of conservative hip prosthesis in accordance with the invention, installed in a resected femur;

Figure 3a is a similar view on a smaller scale of the prosthesis highlighting the areas which are important for bone growth stimulation and integration;

Figure 4 is a longitudinal section similar to Figure 3, of a second embodiment in accordance with the invention;

Figure 4a is a section on a smaller scale of a modification of the embodiment shown in Figure 4.

The following description refers particularly to the embodiments of the invention shown in Figures 3, 3a, 4 and 4a. In order to insert the device, the femoral head and the upper part of the neck of the femur are resected (Figure 2). The higher point of resection provides several important advantages. There is a greater amount of bone preservation than for a conventional total hip, where the resection level is about 10 mm further down into the femur than that shown in Figure 2. At the other extreme, for a surface replacement where most of the head is preserved, the drawbacks are loss of bone support and a reduced head offset if the arthritic head is seriously deformed, and resorption of bone underneath the cup due to stress protection as shown in several clinical and laboratory studies. A further advantage of the prosthesis of the invention is that a tapered neck and a modular femoral head can be used, which has many advantages well recognised in surgical practice.

Referring to Figures 3 and 3a, the upper part of the prosthetic device includes a head (1) and neck (2), which is similar to that used in a conventional total hip prosthesis. The parts of the device which interface with the bone comprises a collar (3) which interfaces against the resected bone surface, a barrel (4) which locates in a hole reamed into the trabecular bone, and a spigot (5) which passes through a hole drilled through the lateral cortex of the femur. Stabilisation for the distal end of the barrel is provided by spigot (5), which is a close fit in the hole in the cortical bone beneath the greater trochanter (6). This Spigot can itself have small flutes with cutting edges for engaging in the cortical bone, thereby providing greater resistance to motion. The Spigot will provide enhanced stability for the entire device, an important factor

considering that implant-bone interface micromotion is detrimental and causes the formation of fibrous tissue, which is itself detrimental to fixation.

One important principle of the prosthesis of the invention is to transfer the forces from the femoral head (1) and from the muscles to the femur in as physiological a manner as possible. This is shown with reference to the trabecular structures, which indicate the lines of action of the forces, while the magnitudes of the forces can be estimated from the trabecular density lines. In the normal femur, the forces on the femoral head are located on an area at the superior region of the femoral head and are transmitted to the medial cortex by a fan of trabeculae. In the prosthesis of this invention, the function of these trabeculae is replaced by two regions. First, by the collar (3) located on the resected neck surface, and secondly by the Barrel locating against the medial neck region (including the anterior and posterior aspects of this region). The Collar is shaped to fit the resected bone surface, being preferably generally elliptical with the major axis substantially vertical but with an anterior bias.

In the lower region of the greater trochanter, a set of trabeculae can be seen streaming towards the femoral neck. These trabeculae are believed to transmit forces generated by the abductor muscles and by other muscles such as the ilio-tibial band wrapping around the greater trochanter. The device of this invention is designed so that the end of the barrel is generally conical as shown at (7), providing a large surface area to interface with this set of trabeculae. It has been shown in many other implants that bone is attracted to convex surfaces and hence it is expected that trabeculae will strongly attach to the end of the barrel. This has been demonstrated in animal studies.

The design of the embodiments shown in Figures 4 and 4a is similar to that shown in Figures 3 and 3a, and equivalent parts are indicated by the same reference numerals. The differences are discussed below.

Hence, surfaces have been designated which have the primary function of transmitting forces between trabecular bone and the implant. These areas, shown particularly in Figure 3a and 4a are the lower surface of the collar, the proximal-medial region of the barrel, and the lower end of the barrel. On all of these surface areas (8), features are desirable which will both stimulate new bone growth and which will enable the trabeculae to remodel onto the surface with rigid fixation to the surface of the implant – see Figures 3a and 4a. These features include the following options. Numerous animal and human studies have shown that such surface features include grit-blasting, small grooves or projections about 0.5-2mm in size, cutting flutes with a triangular section about 0.5-1mm in height, and coatings such as porous or sintered metals, and hydroxyapatite. These can be applied in any combination to improve integration of the prosthesis with the bone.

Further advantages are offered by the device in the surgical technique. The only access required is to the femoral neck. With a suitable guide, the neck is resected at an angle of preferably 35-55 degrees to the horizontal. From finite element analysis and animal studies, this has been shown to be the preferential range for the formation of bone both medially and at the lower end of the barrel The required centerline of the barrel is located on the resected surface and a small hole about 8 mm in diameter is drilled, passing through the lateral cortex. A round hole about 25 mm in diameter is

then drilled and reamed through the neck, towards the lateral cortex. Alternatively, a combined drill with the entire shape of the device can be used in one step. The stem, which is slightly larger in maximum transverse dimension than the hole reamed in the femur, is then tapped into place. The Barrel is preferably made slightly tapered by about 0.5-1.0 mm to maintain tightness along its entire length as it is introduced. The cutting flutes will cut their own track in the trabecular bone. Unlike some other conservative designs indicated in Figure 1, the implant according to the invention does not require access to the lateral cortex. This reduces the surgical exposure and will reduce the recovery time for the patient.

Some variations in features of the device are shown in Figures 4 and 4a. It can be seen that in this case the tapered portion (7) between the barrel and the spigot is shorter than in Figure 3. Also, as shown in Figure 4a, the tapered intermediate portion may have various forms and may, for example, be straight or rounded (e.g. at 9) when viewed in cross-section.

Additional fixation means may be employed for improved stability of the stem or Barrel within the femur. This may be particularly helpful to provide greater initial stability before osseointegration develops. Preferably, such additional or auxiliary fixation is inserted within the femoral neck in order to avoid the need for surgical access to the lateral cortex. One type of fixation of this kind (in this case a bolt or screw (10), fixed obliquely into and engaging in a threaded hole in the barrel) is shown in Figure 4.

It will be seen that the stem, including the barrel (4), is preferably generally straight which makes its insertion easier, especially location of the spigot into a through or blind hole in the lateral cortex. However, a small degree of curvature would be tolerable.

The prosthesis is preferably designed as a press-fit implant. However, bone cement may be used as an aid to fixation.

Although not shown in the Figures, the socket provided for insertion into the acetabulum is preferably formed from ultra-high molecular weight polyethylene, with a cobalt-chromium metal shell liner for lower wear and reduced thickness of the socket.

CLAIMS:-

1. A conservative hip prosthesis which comprises a stem for introduction into the femur, a collar for abutment on a resected surface of the femoral neck and a neck portion for carrying a head, the stem being in the form of a generally cylindrical barrel portion having a distal projection for engagement in the lateral cortex, wherein an intermediate portion between the distal projection and the barrel portion is tapered towards the distal end.

2. A prosthesis as claimed in claim 1 wherein the intermediate portion is shaped as a generally right circular or elliptical cone.

3. A prosthesis as claimed in claim 1 wherein the intermediate portion has rounded sides when viewed in longitudinal section.

4. A prosthesis as claimed in any one of the preceding claims wherein the barrel portion is tapered towards the distal projection to a degree which is less than that of the intermediate portion.

5. A prosthesis as claimed in any one of the preceding claims in which the surface of the barrel portion is formed with slots, slits, grooves, projections or holes and/or has a porous, sintered or hydroxyapatite coating in order to stimulate the osseointegration of the prosthesis into the femur.

6. A conservative hip prosthesis comprising a stem portion, a collar portion and a neck portion, wherein the stem portion is formed with longitudinal cutting means so that on introduction into the femur, the cutting means cut into the bone thus improving stability of the prosthesis in the femur.

7. A prosthesis according to claim 6 wherein the cutting means comprise a plurality of flutes extending longitudinally of the stem portion.

8. A prosthesis as claimed in claim 6 or 7 wherein the stem includes a distal spigot for supporting the stem portion in a hole in the lateral side of the femur.

9. A prosthesis as claimed in any one of claims 6 to 8 wherein the stem is stabilised by a bolt or screw adapted for insertion obliquely into the stem from the head of the femur.

10. A prosthesis as claimed in any one of claims 6 to 9 wherein the stem is substantially cylindrical in cross-section.

11. A conservative hip which comprises a modular head on a neck, attached to a collar which is adapted to locate on the surface of the lower femoral neck which has been resected at 35-55 degrees to the horizontal, the head being attached to a barrel which projects towards the lateral cortex, the barrel being distally tapered, and having a distal spigot for projection into a hole in the lateral cortex; the surfaces of the barrel and collar being adapted to transmit force in a similar manner to that of the trabecular bone within the upper femur.

12. A hip as claimed in claim 11 wherein the barrel is provided with longitudinally extending cutting flutes.

13. A hip as claimed in claim 11 or 12 wherein the surface of the barrel is formed with small depressions, slots or grooves and/or provided with an hydroxyapatite coating to encourage osseo integration.

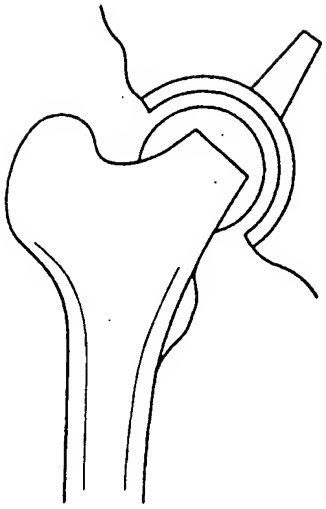

Fig. 1A

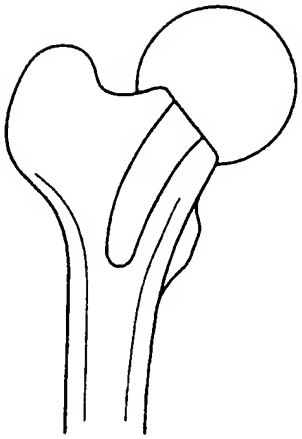

Fig. 1B

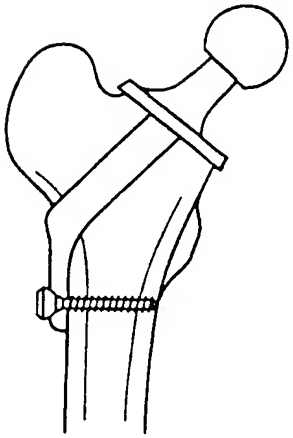

Fig. 1C

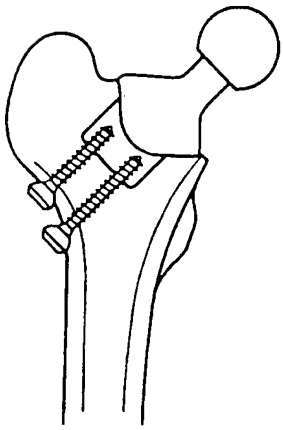

Fig. 1D

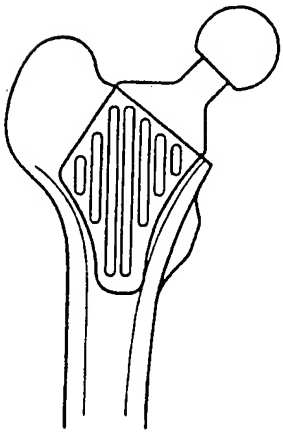

Fig. 1E

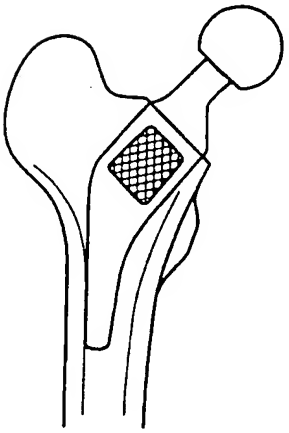

Fig. 1F

CONVENTIONAL HIP REPLACEMENT

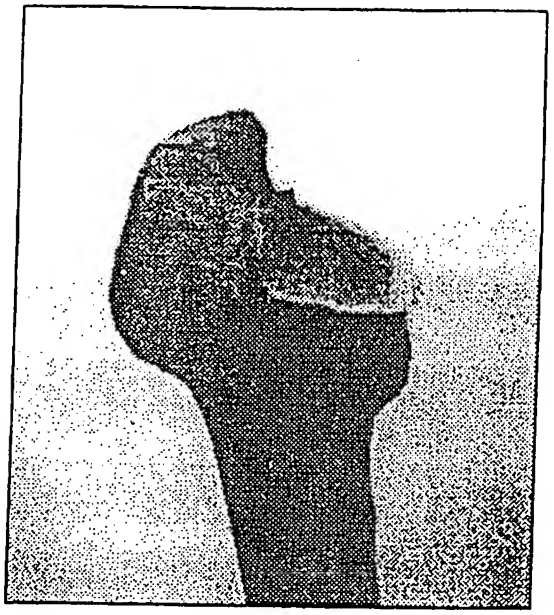

Fig.2A

CONVENTIONAL HIP REPLACEMENT

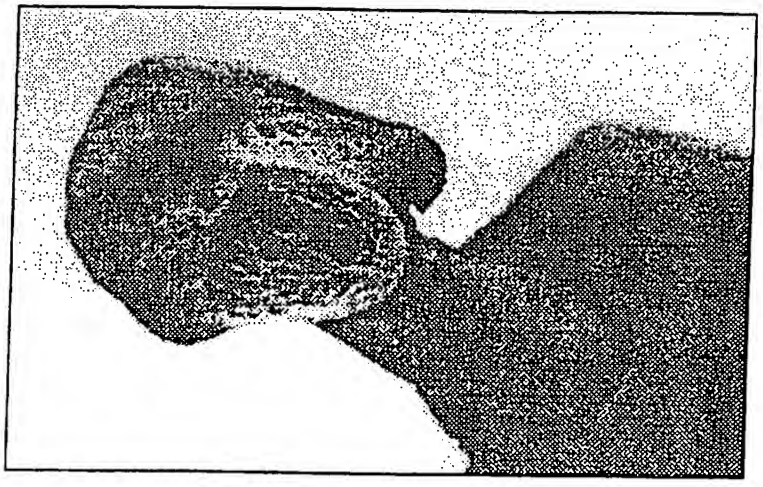

Fig.2B

CONSERVATIVE HIP REPLACEMENT

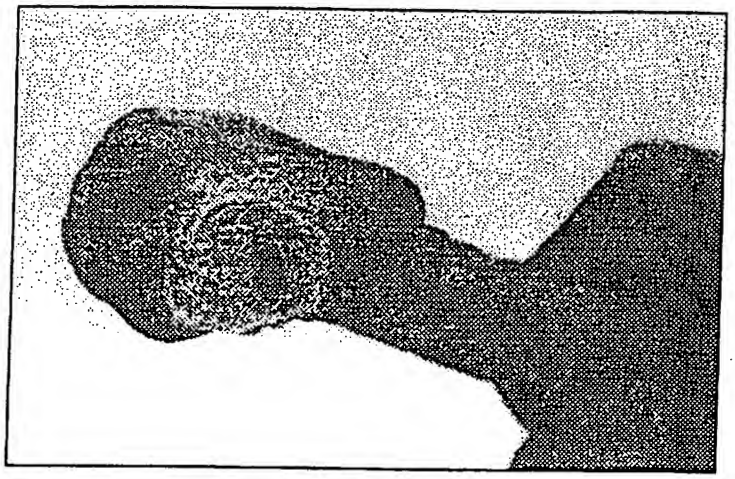

Fig.2C

CONSERVATIVE HIP REPLACEMENT

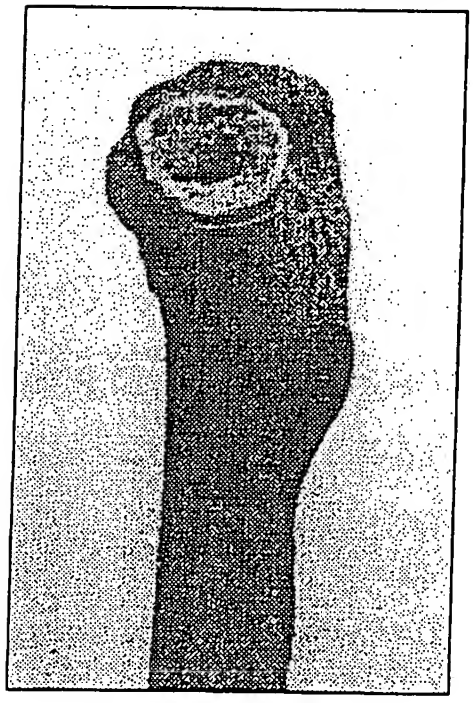

Fig.2D

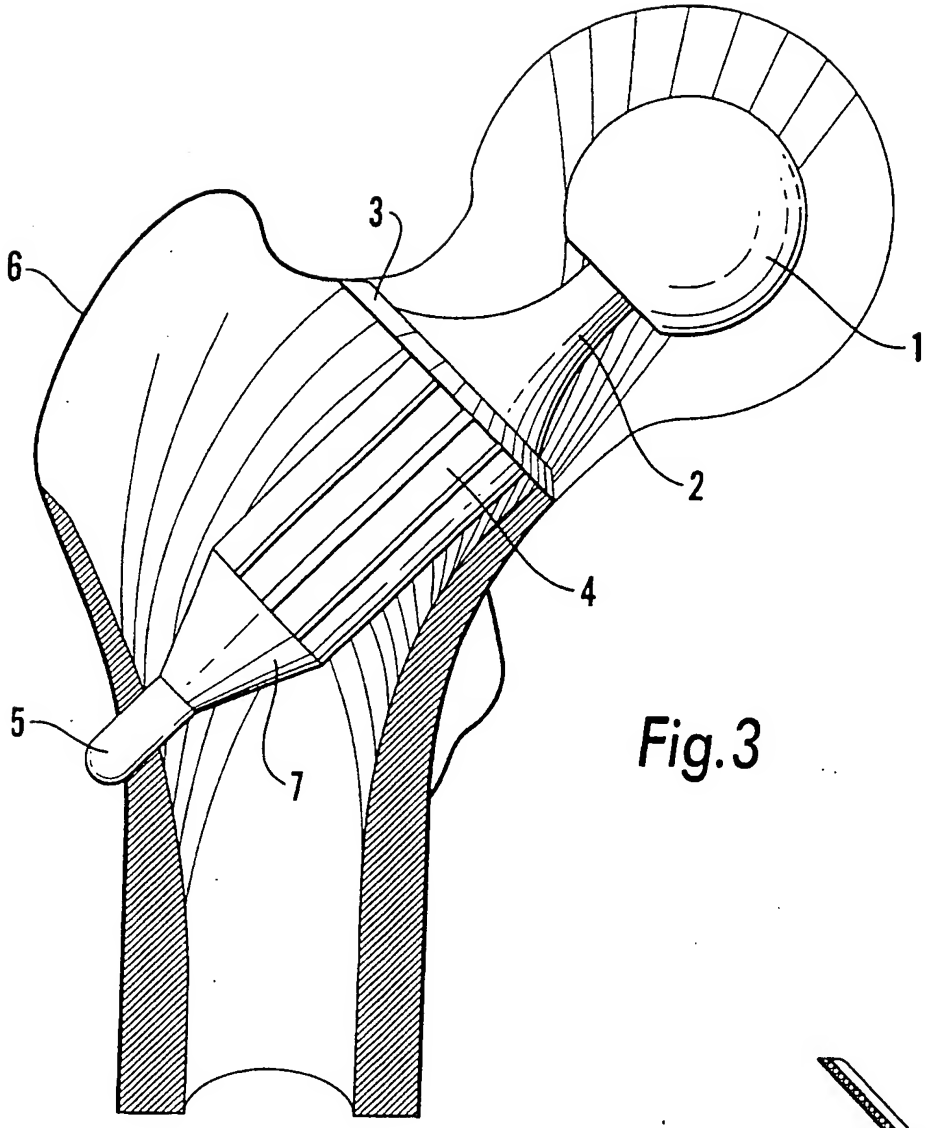

Fig.3

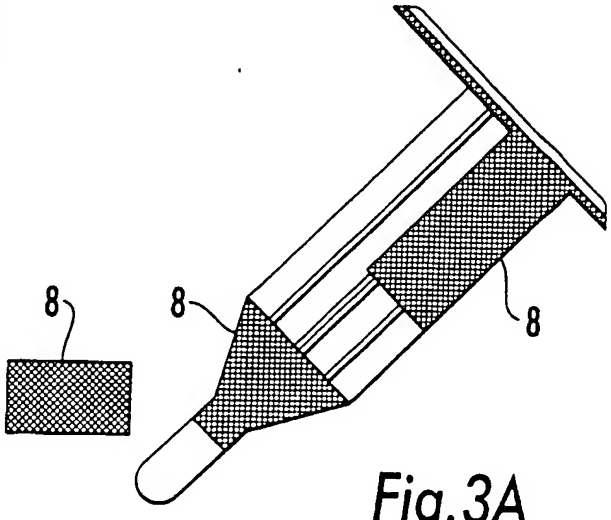

Fig.3A

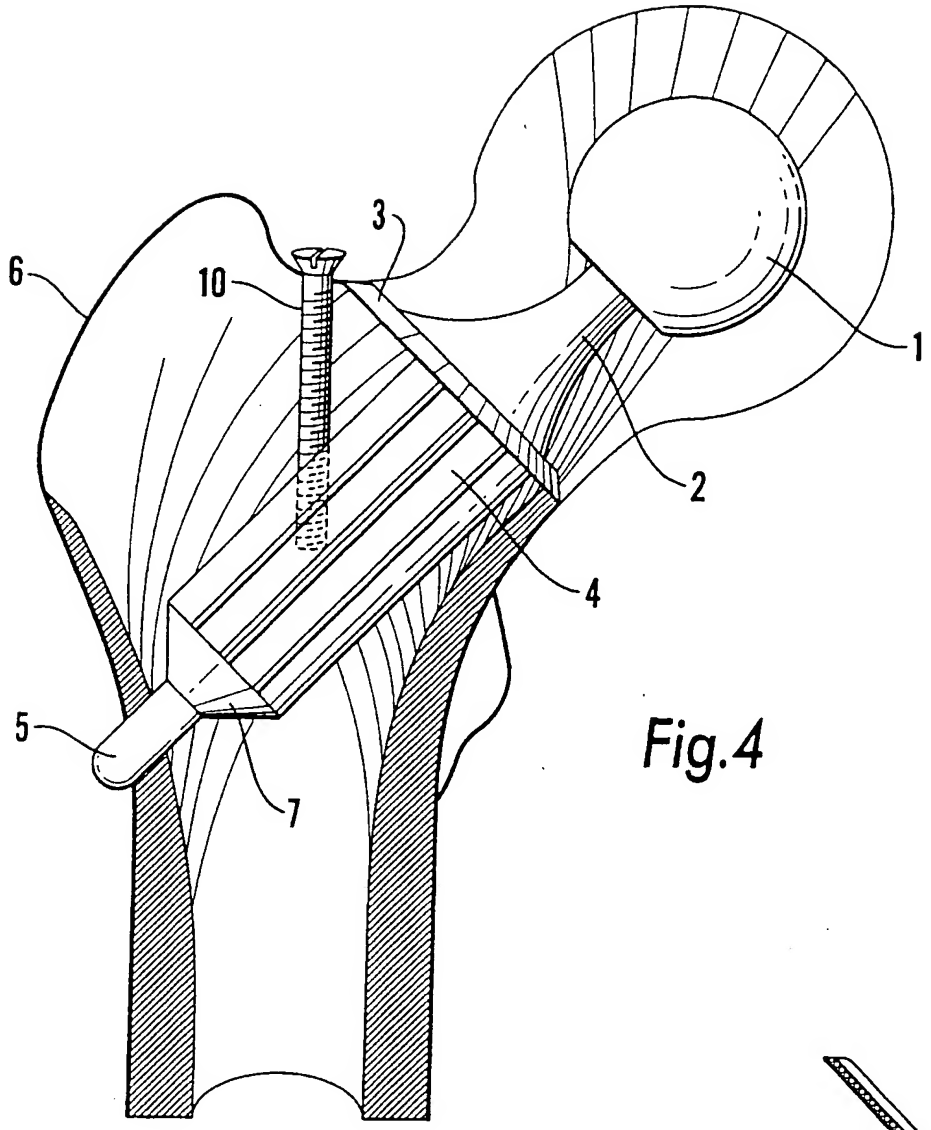

Fig.4

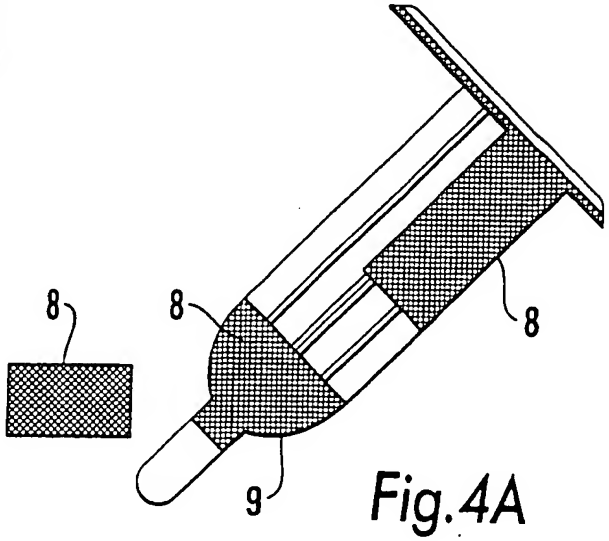

Fig.4A

INTERNATIONAL SEARCH REPORT

Intern ial Application No
PCT/GB 00/03221

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 25939 A (CARLSSON LARS ;WENNBERG STIG (SE); ASTRA AB (SE); ROESTLUND TORD () 24 July 1997 (1997-07-24) claim 1; figures 2,7	1,2,5,6, 8,10,11, 13
A	---	3,7,12
X	GB 2 033 755 A (RAMBERT ANDRE;BOUSQUET G) 29 May 1980 (1980-05-29) claims 1,4; figure page 2, line 27 - line 31	11,13
A	---	1-6,8,10
A	EP 0 099 167 A (CARBOMEDICS INC) 25 January 1984 (1984-01-25) claim 1; figures 1-7	1,5,11, 13

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[X] Further documents are listed in the continuation of box C. [X] Patent family members are listed in annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 December 2000	18/12/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Stach, R

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Intern ıal Application No
PCT/GB 00/03221

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	FR 1 063 680 A (VAN STEENBRUGGHE) 5 May 1954 (1954-05-05) figures 2-4	1-3,5,6, 8,10,11, 13
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